

K203004 ACIST CVi1 Contrast Delivery System, ACIST CVi Contrast Delivery SystemDec 17, 2020
77 days to decisionK203004 · Product code: DXT · General Hospital
Source: <https://www.510kdatabase.net/k203004/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Oct 1, 2020
Decision date	Dec 17, 2020
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Acist Medical Systems, Inc.
Location	Eden Prairie, MN, US
Contact	Jeff Koll
510(k) history	14 submissions · 14 cleared · 2001-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203004/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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